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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Charmaine K. Harris; Joseph J. Klein	Confirmation No.	3255
Serial No.:	10/773,121	Filed:	February 5, 2004
Examiner:	Alyssa M. Alter	Group Art Unit:	3762
Docket No.:	1023-270US02	Customer No.:	28863
Title:	PERCUTANEOUS FLAT LEAD INTRODUCER		

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicants respectfully request a pre-appeal brief review of the above-referenced application. It is Applicants' position that the Examiner has failed to establish a *prima facie* case of obviousness of claims 1-5, 7-40 and 42-50 under 35 U.S.C. § 103(a) in the Final Office Action dated March 6, 2007. For this reason, Applicants respectfully submit that the rejection under 35 U.S.C. § 103(a) is improper and must be reversed. Applicants do not assert that these are the only errors that the Examiner has made, nor do Applicants waive any arguments that may be asserted in an Appeal Brief.

As a preliminary matter, Applicants request that the Examiner review the Information Disclosure Statement mailed by Applicants on March 6, 2006, and initial the included 1449 form.

Claim Rejection Under 35 U.S.C. § 103

In the Office Action, the Examiner rejected claims 1-22 and 24-50 under 35 U.S.C. § 103(a) as being unpatentable over US 2002/0147485 by Mamo et al. (Mamo) in view of US 6,146,371 to DeWindt et al. (DeWindt). Applicants note that claims 6 and 41 are not currently pending. The Examiner also rejected claim 23 under 35 U.S.C. § 103(a) as being unpatentable over the modified Mamo in further view of US 5,255,691 to Otten (Otten).

Applicants respectfully request reversal of these rejections, as the cited references do not include teachings that would have made the claimed invention obvious to one of ordinary skill in the art.

Exemplary features of the independent claims not taught or suggested by the cited references are individually addressed below.

Independent Claims 1, 16, 38, 46 and 49 – *"[a] dilator . . . having a substantially conical distal tip, wherein at least a portion of the conical distal tip has a substantially oblong cross-section"*

Each of the pending independent claims recites a dilator having a substantially conical distal tip, wherein at least a portion of the conical distal tip has a substantially oblong cross-section. The cited references, Mamo and DeWindt, fail to disclose or suggest such a feature. For example, the Office Action admitted that Mamo fails to disclosure such a feature. DeWindt fails to even *discuss* a dilator.

Instead, DeWindt discloses a cannula for use in conducting fluid to or from a body.[1] The DeWindt cannula is not an elongated dilator. Accordingly, neither Mamo nor DeWindt discloses or suggests an elongated dilator, wherein at least a portion of the conical distal tip has a substantially oblong cross-section.

Furthermore, the teachings of DeWindt would not have suggested modification of the shape of the Mamo dilator to a person of ordinary skill in the art. The Office Action stated that the motivation to modify the dilator of Mamo with the oblong or oval shape of DeWindt would be to utilize available space more efficiently. DeWindt teaches use of an oval shape in a cannula to provide an equivalent flow rate to that of a round cannula, while not extending as far toward the center of an access aperture, which is helpful to provide space outside of the cannula for other uses of the access aperture.[2]

This teaching would not have suggested any modification of the Mamo dilator. Use of the Mamo dilator does not involve considerations of flow rate. Moreover, use of the Mamo dilator does not require any space outside of the dilator but within an access aperture.[3] The cross section of the Mamo dilator is circular, which is consistent with common practice. One benefit

[1] *See,* e.g., DeWindt et al., column 1, lines 41-42.
[2] DeWindt et al., column 3, line 66 – column 4, line 5.
[3] *See,* Mamo et al. FIG. 6i and paragraph [0085].

PAGE 5/9 * RCVD AT 8/10/2007 11:24:14 AM [Eastern Daylight Time] * SVR:USPTO-EFXRF-5/17 * DNIS:2738300 * CSID:6517351102 * DURATION (mm-ss):01-56

of a round dilator is to minimize the surface area of a dilator, and therefore the area of tissue-dilator contact within a patient, for the volume of dilation provided by the dilator. The DeWindt teachings do not provide a person of ordinary skill any reason to deviate from this common practice.

It appears that the Office Action found DeWindt to be relevant *merely* because it discloses an oval shape. A person of ordinary skill would not have considered any feature of the cannula disclosed in DeWindt to be relevant to a dilator as disclosed in Mamo. The Office Action provided no logical rationale or evidence as to why a person of ordinary skill would have turned to the DeWindt cannula for modification of the Mamo introducer. Accordingly, it appears that the Office Action impermissibly used Applicant's disclosure as a blueprint to combine attributes of two unrelated devices, and thereby reproduce the Applicant's invention.

Independent Claims 1 and 46 – *"wherein the sheath comprises a material that is substantially deformable"*

The Office Action cited dilators 42 disclosed by Mamo as being equivalent to an elongated sheath, wherein the sheath comprises a sheath material that is substantially deformable. In support of this characterization, the Office Action pointed to page 4, paragraph [0074] of Mamo, which states in part, "The dilators 42 can be metal or plastic . . ." The Office Action then states, "Since the dilator, which includes both the dilator body and dilator sheath, can be constructed from plastic, the sheath and dilator are both deformable."

The conclusion that because dilators 42 can be plastic, Mamo teaches that dilators 42 may be deformable is not logical to the extent that not all plastics are substantially deformable. For this reason, further context regarding the statement that dilators 42 can be plastic is required to logically conclude that Mamo teaches dilators 42 may comprise a material that is substantially deformable, as claimed.

The disclosure of Mamo provides context that suggests that plastic used to form dilators 42 would be substantially rigid, not substantially deformable. For example, as shown in FIG. 9d and described in paragraph [0100] of Mamo, "guide wire 44 is stiff and straight and is long enough so that the dilator 42' can be inserted over the guide wire 44 outside of the patient's skin." FIG. 9d illustrates that dilator 42' is perfectly straight. From this context, one of skill in the art

PAGE 6/9 * RCVD AT 8/10/2007 11:24:14 AM [Eastern Daylight Time] * SVR:USPTO-EFXRF-5/17 * DNIS:2738300 * CSID:6517351102 * DURATION (mm-ss):01-56

would understand that dilator 42' should be made of a stiff material, not substantially deformable as claimed. As another example of how the context of Mamo demonstrates that plastic used to form dilators 42 would be substantially rigid, a dilator that is substantially deformable would not function in the same manner as one that is stiff. However, Mamo fails to note any functional difference between a dilator that is metal, which is presumably stiff, and a dilator that plastic, e.g., when the possibility is mentioned in paragraph [0074]. In this manner, Mamo clearly fails to teach or suggest the feature of an elongated sheath, wherein the sheath comprises a sheath material that is substantially deformable as claimed.

DeWindt also fails to teach or suggest the feature of an elongated sheath, wherein the sheath comprises a sheath material that is substantially deformable.

Independent Claim 16 – *"introducing a stimulation lead to the target site within the epidural region via the sheath"*

The Office Action fails to address the above element of claim 16. Furthermore, Mamo and DeWindt fail to disclose or suggest inserting a stimulation lead introducer into an epidural region proximate a spine of a patient via a guidewire. In contrast, Mamo discloses implantation of a sacral stimulation lead through a foramen of the sacrum in a patient.[4]

Independent Claim 38 – *"wherein the dilator lumen has a substantially oblong cross-section"*

The Office Action fails to address the above element of claim 38. Furthermore, Mamo and DeWindt fail to disclose or suggest a dilator for widening a path for a stimulation lead to travel through an epidural region proximate a spine of a patient. In contrast, Mamo discloses a dilator for implantation of a sacral stimulation lead through a foramen of the sacrum in a patient.[5]

[4] Mamo et al., abstract.
[5] Mamo et al., abstract.

PAGE 7/9 * RCVD AT 8/10/2007 11:24:14 AM [Eastern Daylight Time] * SVR:USPTO-EFXRF-5/17 * DNIS:2738300 * CSID:6517351102 * DURATION (mm-ss):01-56

Independent Claims 46 and 49 – *"wherein a distal end of the stimulation lead has a substantially oblong cross-section and includes at least one electrode"*

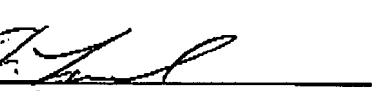
The Office Action fails to address the above element recited by claims 46 and 49. Furthermore, Mamo and DeWindt fail to disclose or suggest a kit including a stimulation lead, wherein a distal end of the stimulation lead has a substantially oblong cross-section and includes at least one electrode. In contrast, Mamo discloses a stimulation lead having a generally round cross-section.[6]

Dependent claims 2-15, 17-37, 39-45 and 47, 48 and 50 are patentable over the applied references for at least the reasons discussed above with respect to independent claims 1, 16, 38, 46 and 49, from which they depend. With respect to claim 23, Otten fails to overcome the deficiencies of Mamo in view of DeWindt as discussed with respect to independent claim 16. In light of the clear differences between the independent claims and cited references, Applicant reserves further comment with respect to the dependent claims.

CONCLUSION

For at least the reasons stated above, all rejections are improper and must be reversed. By setting forth the clear grounds of error, Applicants do not assert that these are the only errors that the Examiner has made, nor do Applicants waive any arguments that may be asserted in an Appeal Brief. Applicants request a review and a panel decision that promptly resolves the issues in Applicants' favor and eliminates the need for an Appeal Brief. Please charge any additional fees or credit any overpayment to deposit account number 50-1778.

Date: August 10, 2007

By: 

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[6] *See*, e.g., Mamo et al., FIGS. 5i-5k.

PAGE 8/9 * RCVD AT 8/10/2007 11:24:14 AM [Eastern Daylight Time] * SVR:USPTO-EFXRF-5/17 * DNIS:2738300 * CSID:6517351102 * DURATION (mm-ss):01-56